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No. 06-1047

In The

Supreme Court of the United States

LISA ANN PAFFORD and RICHARD LEON PAFFORD, PARENTS AND NEXT FRIENDS OF RICHELLE LORRAE PAFFORD, a minor,

Petitioners,

-vs.-

MICHAEL O. LEAVITT, SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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PETITIONERS' REPLY TO BRIEF FOR THE RESPONDENT IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the 1989 Technical Amendments granting "trial" jurisdiction to special masters under the National Childhood Vaccine Injury Compensation Act of 1986, 42 U.S.C. 300aa-10 *et seq.*, constituted the creation of an "agency" of the Executive Department which must be structured to conform with the Appointments Clause.

2. Whether *ad hoc* adjudication in Vaccine Act cases—by "inquisitorial" officials empowered to enter final orders—violates the Fifth Amendment's Due Process Clause, in the absence of procedural safeguards akin to those provided by the Administrative Procedure Act, 5 U.S.C. Subchapter II, §§ 551 *et seq.*

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STATEMENT

1.a. In 1986, after years of debate, Congress enacted the Vaccine Act, 42 U.S.C. §§ 300aa-1 *et seq.* "Principal findings" made by the Committee on Energy and Commerce concluded that "[t]he Federal government has the responsibility to ensure . . . that all children who are injured by vaccines have access to sufficient compensation for their injuries.' H.R. Rep. 99-908, 5, *reprinted* 1986 U.S.C.C.A.N. 6344, 6346. Accordingly, compensation provisions were enacted at §§ 300aa-10 *et seq.*, whereby a special master as an "adjunct" to the Court would review the petition, create the record, and "report" to United States District Courts, which were granted jurisdiction to make awards of compensation. In 1987, the Court of Claims was substituted for district courts. P.L. 100-203, § 4307 (42 U.S.C. § 300aa-12).

The Vaccine Act "was enacted by Congress in response to the large number of law suits against vaccine manufacturers . . . and the impact these claims had on vaccine manufacturers resulting in their unwillingness to continue producing vaccines." *Benedict v. Secretary of DHHS*, 29 Fed.Cl. 587, 593 (1993). Thus, "[t]he motivating factor was to shield 'manufacturers from exposure to liability [including litigation costs] resulting from the small . . . incidence of unavoidable injury or death from widespread use of the vaccine[s].'" *Ibid.*, quoting *Amendola v. Secretary of DHHS*, 989 F.2d 1180, 1186 (Fed. Cir. 1993) at 1186. *See*, H.R. Rep. 99-908, 4, 1986 U.S.C.C.A.N. 6345 ("While most of the Nation's children enjoy greater benefit from immunization programs, a small but significant number have been gravely injured. These children are often without a source of payment or compensation for their medical and rehabilitative needs, and they and their families have resorted in greater numbers to the tort system for some form of financial relief").

Contemplating simple and straight-forward "no-fault" compensation proceedings, the Report stated, "The entire proceeding—from date of filing through Special Master

proceedings and court review—is to take place as expeditiously as possible and, in no case, should take more than one year." *Id.*, p. 17, 1986 U.S.C.C.A.N. 6358. The Committee also noted that "much of the equity in limiting compensation and limiting other remedies arises from the speed and reliability with which the petitioner can expect judgment; without such quick and certain conclusion of proceedings, the compensation system would work an injustice upon the petitioner." *Ibid.*

The 1987 legislation (Pub. L. No. 100-203) moving jurisdiction to the Claims Court did not abandon the aim of "a quick and generous compensation system." H.R. Rep. 100-391(I) 690, *reprinted* 1987 U.S.C.C.A.N. 2313-364, describes "the Committee's intention to create a compensation system that is speedy and generous enough to dissuade petitioners from going on to court[1]." *Id.*, p. 691, 1987 U.S.C.C.A.N. at 2313-365. The legislative intent document accompanying the 1989 Technical Corrections—which created the constitutional problems at issue—reiterated that "Special masters are to make their decision on the award and amount of vaccine compensation within 240 days." H.R. Conf. Rep. 101-386, 101st Cong., 1st Sess. 509, 516, *reprinted* 1989 U.S.C.C.A.N. 3018, 3119. The technical amendments allowed for "suspensions" of the time limits, but "not to exceed 150 days in total." *Ibid.*; 42 U.S.C. § 300aa-12 (d) (3). However, by 1993 the Federal Circuit had authorized masters to suspend proceedings for as long as necessary to complete proceedings, reasoning that an "inevitable announcement that [a master] could no longer entertain the petition" was "clearly . . . not intended by Congress." *Widdoss v. Secretary of DHHS*, 989 F.2d 1170, 1175 (Fed. Cir. 1993).

b. On March 24, 1998, Richelle Lorraine Pafford was inoculated in Cheyenne, Wyoming, with multiple vaccines.

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[1] *See also Leuz v. Secretary of DHHS*, 63 Fed.Cl. 602, 612 (Fed.Cl. 2005) ("Passage of the Vaccine Act was motivated by a concern that tort law remedies were an inconsistent and unsatisfactory approach to compensating individuals injured by vaccines").

By April 30, 1998, Richie had developed "soJRA," a debilitating and chronic arthritis[2]. Pet. App. 7. *infra.*

Richie's petition was filed on March 22, 2001. The master's Decision—even without a damages proceeding—took over three years, and issued June 16, 2004. (Pet. App. 1.) Review in the courts below, seeking to overturn a manifest miscarriage of justice, was not completed until October 24, 2006.

As noted in the Petition, the master's "decision" was the first formal notice that an unpleaded "time of onset" issue would be dispositive. Due Process objections were argued and preserved in both reviewing courts. C.A. Br. 26-36, CFC Mem. Ob. 30, 39, 40-43.

ARGUMENT

The Secretary asserts (Opp.Br. 7) that the Vaccine Act is "carefully crafted," but fails to adequately respond to the Petitioners' cogent showing that it has been crafted by amendment to be unconstitutional. And the Secretary invokes incorrect legal standards. For example, seeking to avoid the Appointments Clause requirement for presidential appointment with Senate approval, the Secretary asserts that masters can be hired and fired by the appointing court. But the Secretary fails to show that their **work** is "supervised."

The Secretary's response to the Petition also ignores completely the "inquisitorial" nature of the agency created by the Act, failing even to acknowledge its Article I nature. The Secretary's brief is silent as well regarding the problems with the *ad hoc* nature of each and every Program adjudication. And this is the shortcoming in the Secretary's entire

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[2]Richie's multiple inoculations included Rubella vaccine, which underlies a defined "Table" injury labeled as "Chronic Arthritis." Contrary to the Secretary's assertion (Opp.Br. 4), it was not the "timing of onset"—in Richie's case, less than six weeks—which deprived Richie of the Table presumption. "Table time" for Chronic Arthritis contemplates injury onset within 7-42 days, exactly as Richie experienced. But the Secretary enacted the Table to exclude Juvenile Rheumatoid Arthritis from the injury definition. Aids and Qualifications to Interpretation, ¶ 5, 42 C.F.R. 100.3.

argument. Rather than to address the specifics of the Petition, the Secretary relies on inaccurate generalizations.

Petitioners have made the showing that deferential review is part and parcel of the Act's evisceration of the power of the Court of Federal Claims (CFC). The Secretary (Opp.Br. 10) finds this "difficult to square" with petitioners' legal conclusion, *i.e.*, that in the absence of APA-type procedural protections, there is nothing to prevent the masters' "agency" from depriving vaccine-injured children of constitutional Due Process. Thus, the government's argument seems to be that if the "agency" standard of review is so bad, why would petitioners advocate for the "agency" standard of procedural fairness? This *non sequitur* reveals the Secretary's argument for rhetoric, instead of reason.

The Secretary even posits (*ibid.*) that the petitioner's "right" to pursue civil litigation—the very situation the Act was **most** concerned with preventing—is an adequate protection against the **years** of scorched-earth litigation which the Vaccine Program's lack of precedent and procedural fairness enabled the Secretary to foist upon Richie Pafford's family, and as occurs with every petitioner. But the compensation remedy was created as the incentive to abjure civil recourse. A fair proceeding would have resulted in a award of that compensation remedy.

Further, the government protests that the structural constitutional claims herein were not made below, while also asserting that the Due Process claims which **were** made below "are not fairly included in the question presented." None of the Secretary's arguments hold water.

1. The Secretary misreads *Edmond v. United States*, 520 U.S. 651 (1997), to assert (Opp.Br. 8) that the "higher rank" of the CFC judges—who appoint masters under 42 U.S.C. § 300aa-12—renders the masters "inferior officers" under the Appointments Clause. The Secretary implies (Opp.Br. 9.) simply that the CFC judges lack the "time or resources" to supervise the masters. In point of fact, however, the CFC judges lack the **power** to supervise. The Secretary also asserts that the standard of review is not "all that

deferential." (*Id.*, 9-10.) The Secretary is wrong on both counts.

As to the former, the jurisdictional distinction, the Federal Circuit affirms that the special master is "the key decision-maker." *Munn v. Secretary of DHHS*, 970 F.2d 863, 870 (Fed. Cir. 1992). And the standard of review, the Circuit proclaims, is "well understood to be the most deferential possible." *Ibid.*, citing M. Davis, A Basic Guide to Standards of Judicial Review, 33 S.D.L.Rev. 469, 476 (1988) and 2 Childress and Davis, Standards of Review § 15.7 (1986).

The *Edmond* test, moreover, does not depend on "rank." It depends on function:

> It is not enough that other officers may be identified who formally maintain a higher rank, or possess responsibilities of a greater magnitude. If that were the intention, the Constitution might have used the phrase 'lesser officer.' Rather, in the context of a Clause designed to preserve political accountability relative to important Government assignments, we think it evident that ***"inferior officers" are officers whose work is directed and supervised*** at some level by others who were appointed by Presidential nomination with the advice and consent of the Senate.

Id., 520 U.S. 651, 662-663, emphasis added. This Court cannot help but find that masters under the Vaccine Act are **not** inferior officers by functional definition[3].

2. The Secretary argues that preservation of civil tort actions by the Act endows Richie Pafford's family with "***greater*** rights than a dissatisfied party in APA proceedings." (Opp.Br. 10, emphasis in original.) Only the

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[3] The government's footnote reference (Opp.Br. 9) to *United States v. Raddatz*, 447 U.S. 667 (1980) and *Mathews v. Weber*, 423 U.S. 61 (1976) should provide it no comfort. These cases does not validate review of an inferior official's work with the deference afforded under the Vaccine Act.

word "dissatisfied" dilutes the specious nature of the argument. Unlike Vaccine Act petitioners, APA supplicants are entitled to notice of legal authority and the matters of fact and law asserted. 5 U.S.C. § 554 (b). This includes "prompt notice of issues controverted in fact or law." The existence of an issue like undisclosed "time frame" element would require an opportunity to present rebuttal evidence. 5 U.S.C. § 556 (d)[4].

The APA contemplates full and true disclosure of the facts. It contemplates an opportunity to address any issue. There is no honor for Congressional intent in the Secretary's suggestion that Program petitioners, dissatisfied with the government's administration of the Act, should sue the selfsame beneficial industry the Act was created to protect and nurture.

The Congressional intent document recognized the enormous difficulty of tort litigation, in advocating a no-fault remedy, stating that under the tort system, "opportunities for redress and restitution are limited, time-consuming, expensive, and often unanswered." H.R. Rep. 99-908 at 6, 1986 U.S.C.C.A.N. 6347. Congress continued, *ibid.*, "Lawsuits and settlement negotiations can take months and even years to complete. Transaction costs—including attorneys' fees and court payments—are high. And in the end, no recovery may be available. Yet futures have been destroyed and mounting expenses must be met."

In this context—where Richie Pafford is condemned to a life of need because of unfair adjudication—the balancing

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[4] Petitioner does not call for APA procedures as such. The rules of the Social Security system, for instance—itself an "inquisitorial" tribunal—are sufficient because they provide the same fundamental fairness as the APA. *Richardson v. Perales*, 402 U.S. 389, 410 (1971). Thus, in the instant context, "due process of law" conveys the same meaning as "by the law of the land." *Den ex dem. Murray v. Hoboken Land & Improvement Co.*, 59 U.S. 272, 276 (1855). *Certiorari* is appropriate because Vaccine Program adjudication departs so far from the usual and accepted course of judicial (and agency) proceedings, *i.e.*, the law of the land. The manifest injustice begs for plenary review.

test of *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976) mandates consideration for the "the degree of potential deprivation" which is suffered by vaccine-injured children. *Id.*, at 341. The Secretary has offered no countervailing consideration that overcomes the interest in fairness. Nor has the Secretary identified any additional burden which would be imposed by a requirement for the procedural fairness that has been imposed upon every agency of the government except the Office of the Special Masters. It appears, instead, that the Secretary simply wants to maintain the current, great advantage. The Secretary cannot honestly contend that vaccine injury adjudications comport with the Congressional intent.

3. The Secretary's brief is an effort to re-cast and defuse the issues raised by the Petition. To avoid the problem with the allocation of jurisdiction in the agency apparatus created by the 1989 Technical amendments, the Secretary recognizes only the deferential standard of review as the "theory" of petitioners' argument. But the basis for the Appointments Clause problem is more fundamental. It is the grant of trial jurisdiction to the masters[5]. The judges of the CFC are not only stripped of their superior officer status, but relegated to a 120-day window of review jurisdiction[6]. 42 U.S.C. § 300aa-12 (e) (2). Deferential review is part and parcel of the jurisdictional and structural construct which violates constitutional strictures.

The Secretary will not acknowledge that the Office of the Special Masters is an executive-branch "agency." But this

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[5]The Secretary stubbornly insists (Opp.Br. 14) that the Court of Federal Claims is the trial court, and that this is why the lack of precedent, even there, is of no moment. The argument collapses with the realization that the special masters constitute their own "agency."

[6]The settled meaning of the term "special master" is inconsistent with the attributes of the Vaccine Program adjudicators. *See, La Buy v. Howes Leather Co.*, 352 U.S. 249, 256 (1957), holding, "The use of masters is 'to aid judges in the performance of specific judicial duties, as they may arise in the progress of a cause' and not to displace the court." (Citation omitted.)

Article I tribunal wears more than one hat. It is assigned both investigative and adjudicative tasks[7]. And then it assigns both to a single human being, whose say is final in the matter[8]. The courts below ruled that **actual** notice of the pivotal issue—which any agency (or a party appearing before one) would be required to give—was unnecessary.

The difference between the Program's "inquisitorial" framework and the ordinary judicial decision-making process is "pronounced." *See, Sims v. Apfel*, 530 U.S. 103, 110-111 (2000), citing J. Dubin[9], Torquemada Meets Kafka: The Misapplication of the Issue Exhaustion Doctrine to Inquisitorial Administrative Proceedings, 97 Colum. L.Rev.

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[7] Justice Scalia's concurring opinion in *Freytag v. C.I.R.*, 501 U.S. 868 (1991)— cited by the Secretary(Opp.Br. 8) to argue that a Chief Judge as a "Department Head" could appoint inferior officers—provides abundant authority for the proposition that the Office of the Special Masters is an "agency." *Id.*, pp. 908-922. However, Vaccine Act masters are not appointed by the Chief Judge, and they are not "inferior officers." But their entire "office" is indeed a vaccine injury adjudication agency, allowed to make up the law and procedure as it goes.

[8] While the "multiple hat" model of inquisitorial adjudication in the SSA is inconsistent with the thrust of 5 U.S.C. §§ 554 (d) and 557 (d) (1)—which recognize the danger of mixed investigative and adjudicatory roles—the SSA multilevel, non-adversarial review process sufficiently tends to prevent what the inquisitorial **and** adversarial Vaccine Program did to the Paffords. *See, generally, Richardson v. Perales, supra.*

[9] The allusion to "Kafkaesque" procedures, frequently made by the courts and commentators in discussing the Social Security system, is *a fortiori* apropos to the Vaccine Program. *See*, Dubin, *supra*, at 1293-94, fn. 26, quoting J. Mashaw, Bureaucratic Justice, Managing Social Security Disability Claims 91 (1983), which explains,

> Kafkaesque procedures take away the participants' ability to engage in rational planning about their situation or to make informed choices among alternatives. The participant begins to see himself as an object, subject to infinite manipulation by "the system." In order to be spared this sense of alienation, participants must have adequate notice of the issues to be decided and of the evidence that is related to those issues . . .

1289, 1301-1305, 1325-1329 (1997).

A Social Security ALJ, like a Vaccine Program special master, will "investigate the facts and develop the arguments both for and against granting benefits." *Sims*, at 111. And unlike even the SSA scheme, the Program adjudication afforded no opportunity on the part of the claimant to "come to issue" on a pivotal fact such as the "time-frame" element that defeated Richie Pafford's claim. Thus, the "analogy to judicial proceedings is at its weakest." *Id.*, at 112, citing *Hormel v. Helvering*, 312 U.S. 552, 556 (1941).

Sims cautions against "reflexively 'assimilat[ing] the relation of . . . administrative bodies and the courts to the relationship between lower and upper courts." *Id.* at 110, citing *Shepard v. NLRB*, 459 U.S. 344, 351(1983), and *FCC v. Pottsville Broadcasting Co.*, 309 U.S. 134, 144 (1940). Thus the rationale of *Sims* overcomes the Secretary's urging that the structural objections raised herein should not be reviewed because that were not presented below. *Sims* finds that the prudential reasons which compel the mainstream judicial rule are of little moment in the Court's review of agency issues unrelated to the actual agency determination.

> As this Court stated in *Hormel,* 312 U.S. at 557,
>
> Rules of practice and procedure are devised to promote the ends of justice, not to defeat them. A rigid and undeviating judicially declared practice under which courts of review would invariably and under all circumstances decline to consider all questions which had not previously been specifically urged would be out of harmony with this policy. Orderly rules of procedure do not require sacrifice of the rules of fundamental justice.

CONCLUSION

As Justice Douglas observed, dissenting in *Richardson v. Perales, supra*, 402 U.S. at 413,

> This case is minuscule in relation to the staggering problems of the Nation. But when a grave injustice is wreaked on an individual by

> the presently powerful federal bureaucracy, it is a matter of concern to everyone, for these days the average man can say: 'There but for the grace of God go I.'

Unlike even the SSA proceeding (described *in Sims, supra,* at 112) where there is no appearance or opposition from the government, the Vaccine Act proceeding includes the Secretary, a committed and powerful adversary. In the master, a petitioner faces another potential adversary. With no agency uniformity, no *de novo* judicial review, and the utmost of deference even for inconsistent results, the petitioner is at the whim of the Program.

The petition should be granted.

Respectfully Submitted this 11th day of May, 2007

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